Applicant: Michele Orlando et al. Attorney's Docket No.: 14503-0010US1

Serial No.: 10/506,366 Filed: February 2, 2005

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REMARKS

Claims 37, 39, 42-47, 56, and 74-78 are pending and stand rejected, and claims 57-73 stand withdrawn. In light of the following remarks, Applicants respectfully request reconsideration and allowance of claims 37, 39, 42-47, 56, and 74-78.

Foreign priority

The Examiner noted that the present application claims foreign priority from PCT Application No. PCT/EP03/02084 and German Application No, 10209822.0, which both are in German, and that no translation of the documents into English has been provided.

Applicants respectfully note that a verified English translation of PCT/EP03/02084 was filed with the application on September 2, 2004. The English translation and the verification are available on PAIR. Applicants note that DE 10209822.0 is identical to the PCT application.

<u>Information Disclosure Statement</u>

The Examiner asserted that the Information Disclosure Statement (IDS) filed May 3, 2010 did not comply with 37 C.F.R. § 1.98(a)(2), and stated that the IDS was placed in the application file without consideration.

Although the Examiner did not provide a specific reason why the IDS did not comply with the requirements of 37 C.F.R. § 1.98(a)(2), Applicants believe the deficiency to be the inadvertent submission of only the first page for each of Desig. IDs 9-14. A new IDS and Form PTO-1449 are filed herewith for the Examiner's review. Complete copies of Desig. IDs 9-14 are submitted. Copies of the remaining foreign patent documents and non-patent literature (Desig. IDs 3-8 and 15-24) were submitted with the IDS that was filed on May 3, 2010, and are available in PAIR. Additional copies will be provided on request. Copies of the cited U.S. patent and patent application publication (Desig. IDs 1 and 2) also will be provided on request.

The Examiner is respectfully requested to return an initialed copy of the attached Form PTO-1449 to the undersigned agent.

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Double patenting

The Examiner rejected claims 37, 39, 42-47, 56, and 74-78 on the ground of nonstatutory obviousness-type double patenting, alleging that they are unpatentable over claims 10-19 of U.S. Patent No. 7,258,661 (the '661 patent) in view of U.S. Patent No. 6,011,008 (the '008 patent). The Examiner asserted, for example, that the '661 patent discloses a starch/active-substance conjugate comprising formula (II) recited in claim 10 therein, wherein R" denotes a straightchain or branched alkyl, aryl, or aralkyl group, R-CO- denotes an oxidized substituted or unsubstituted starch radical oxidized at the reducing end group to form a carboxylic acid, and R' is the radical of an active substance, and that the active substance of the '661 patent can be a peptide, protein, antibiotic, nucleic acid, or hormone. The Examiner further asserted that the instantly claimed conjugate of hydroxyalkylstarch and a low molecular weight substance differs from the conjugate of the '661 patent by claiming specific low molecular weight substances, but alleged that '008 patent discloses a conjugate of a polysaccharide and a substance that can be selected from the group consisting of amine containing low molecular weight drug and drug derivatives, and low molecular weight polypeptides and polypeptide analogs (e.g., flucytoxine, trimethoprim, mitomycins, doxorubicin, vasopressin and oxytocin, as recited in claims 3 and 6 of the '008 patent, as well as in claim 37 of the instant application).

The Examiner also rejected claims 37, 39, 42-47, 56, and 74-78 on the ground of nonstatutory obviousness-type double patenting, alleging that they are unpatentable over claims 1-8 and 10 of U.S. Patent No. 7,541,328 (the '328 patent) in view of the '008 patent. The Examiner asserted that the '328 patent discloses a hydroxyethylstarch-protein conjugate, wherein the binding interaction between the hydroxyethylstarch molecule and the protein is a single covalent bond that is the result of a coupling reaction between (i) the terminal aldehyde group of the hydroxyethylstarch molecule and (ii) a primary amino group of the protein to form a Schiff's base, which embraces the conjugate of the instant claims. The Examiner further asserted that the instantly claimed conjugate differs from the starch/active-substance conjugate of the '328 patent by claiming specific low molecular weight substances, but alleged that the '008 patent discloses a conjugate of a polysaccharide and a substance selected from the group consisting of amine

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containing low molecular weight drug and drug derivatives, and low molecular weight polypeptides and polypeptide analogs as set forth above.

Without acquiescing to these rejections and to further prosecution, Applicants submit herewith Terminal Disclaimers over U.S. Patent Nos. 7,258,661 and 7,541,328. In light of these documents, Applicants respectfully request withdrawal of the rejections of claims 37, 39, 42-47, 56, and 74-78 for alleged obviousness-type double patenting.

CONCLUSION

Applicants submit that claims 37, 39, 42-47, 56, and 74-78 are in condition for allowance, which action is respectfully requested. The Examiner is invited to telephone the undersigned agent if such would further prosecution.

Please apply \$280 for the Terminal Disclaimer fees, and any other charges or credits, to deposit account 06-1050.

Respectfully submitted,

Date: November 15, 2010 /Elizabeth N. Kaytor/

Elizabeth N. Kaytor, Ph.D.

Reg. No. 53,103

Customer Number 26191 Fish & Richardson P.C. Telephone: (612) 335-5070

Facsimile: (877) 769-7945

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